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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,319	10/26/2001	Michael R.S. Hill	P-10124.00	3335

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EXAMINER	
OROPEZA, FRANCES P	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,319	HILL ET AL.	
	Examiner	Art Unit	
	Frances P. Oropeza	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/9/06 (Response)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/23/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response

1. In the response of 6/9/06, the Applicant amended at least the independent claims hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 102

2. Claims 20, 23-24, and 26-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Hartlaub (US 6134470). Hartlaub discloses a method and device with a subcutaneous electrode (125) proximate the skin covering the spine, physiological sensors – an activity sensor (342), sensor controls (340), neural stimulator (272) and controllers (270, 244) to detect the precursors to tachyarrhythmias and respond with stimulation of the spinal cord/ spinal roots, pacing therapy and/or a drug delivery system. The therapy is provided for the precursors to tachyarrhythmias, hence the system anticipates the occurrence of a cardiac insult. The spinal cord generator is activated for predetermined time periods, hence the device is capable or teaches neural stimulation prior to onset of the insult, for a period to time after the onset of the insult, or for a time period after termination of the insult. The results of past stimulation are used to perform future stimulation (abstract; figures 1, 2; col. 1 @ 42-52; col. 2 @ 3-15 and 40-53; col. 4 @ 35-47; col. 4 @ 56 – col. 5 @ 7; col. 6 @ 25-54col. 7 @ 47-61; col. 8 @ 66 – col. 9 @ 20; col.9 @ 53-67; col. 11 @ 24-65; col. 12 @ 19-25; col. 13 @ 4-34).

As to claims 20, 31 and 32 and the use of the device with the excitable neural tissue of a portion of the spine, Hartlaub discloses the use of the device with the excitable neural tissue of a

portion of the spine, the spinal cord (col. 1 @ 5-9; col. 4 @ 35-47). Note that the concept of using of the device with the excitable neural tissue of a portion of the spine amounts to an intended use limitation of which the device performs or is capable of performing.

As to claims 20, 31 and 32 and closed loop control of the stimulation system, Hartlaub discloses closed loop control of the stimulation system with input to the control circuit coming from the activity sensor (abstract; col. 1 @ 45-52; col. 1 @ 65 – col. 2 @ 12; col. 6 @ 44-54; col. 9 @ 15-19).

As to claims 21, 31 and 32 and a drug dispensing apparatus/ means for dispensing biologically-active agents, Hartlaub teaches use of a drug dispenser (col. 5 @ 3-7) and incorporates by reference (col. 5 @ 3-13) US 5220917 to Cammilli et al. who teaches a drug dispensing apparatus/ means for dispensing biologically-active agents that delivers the medicament via a catheter (col. 1 @ 62-68).

The Applicant's argument filed 6/9/06 has been fully considered but are not convincing. The Applicant asserts Hartlaub does not address expressly or inherently delivery of a biologically-active substance to the patient. The Examiner disagrees. Hartlaub teaches delivery of a biologically-active substance to the patient (abstract; col. 1 @ 61-64; col. 5 @ 3-13).

Claim Rejections - 35 USC § 103

3. Claims 20-21, 26, 31, 32 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obel et al. (US 5199428) in view of Hartlaub (US 6134470).

Obel et al. disclose a nerve stimulator (108) and pacing therapy (104) to respond to a physiological parameter (pH, SO2 and changes in ST segment) which provides "a meaningful predictor of ischemia" and potential arrhythmias to the controller (100). The therapy is provided for "a meaningful predictor of ischemia" and potential arrhythmias, hence the system anticipates the occurrence of a cardiac insult. A patient activation mechanism is taught (abstract; figure 2; col. 5 @ 25-51; col. 6 @ 39-53; col. 7 @ 5-25; col. 10 @ 3-5).

As to claims 20, 31 and 32 and the use of the device with the excitable neural tissue of a portion of the spine, Obel et al. discloses the use of the device with the excitable neural tissue of a portion of the spine, the "other effective nerves" read as the ganglion stellate associated with the Autonomic Nervous System (col. 1 @ 9-13; col. 3 @ 8-19). Note that the concept of using of the device with the excitable neural tissue of a portion of the spine amounts to an intended use limitation of which the device performs or is capable of performing.

As to claims 20, 31 and 32 and a closed loop control of the stimulation system, Obel et al. disclose a closed loop control of the stimulation system that included the physiological parameter in the loop (abstract; col. 5 @ 25-51; col. 6 @ 39-53; col. 7 @ 5-25).

As discussed in the previous four paragraphs of this action, Obel et al. disclose the claimed invention except for a drug dispensing apparatus/ means for dispensing biologically-active agents that delivers the drugs via a catheter.

Hartlaub teaches cardiac treatment for cardiac insult (therapy is provided for the precursors to tachyarrhythmias, hence the system anticipates the occurrence of a cardiac insult)

using a drug dispenser (col. 5 @ 3-7) for the purpose of adding an additional therapy to treat the patient's condition. Hartlaub incorporates by reference (col. 5 @ 3-13) US 5220917 to Cammilli et al. who teaches a drug dispensing apparatus/ means for dispensing biologically-active agents that delivers the medicament via a catheter (col. 1 @ 62-68). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a drug delivery device that delivers the drugs via a catheter in the Obel et al. system in order to use a proven means of cardiac therapy that can effectively treat cardiac dysfunction using an alternate means to electrical stimulation (abstract; col. 1 @ 53-68; col. 5 @ 3-7).

4. Claims 20, 23-26, 31, 32 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sweeney et al. (US 6272377) in view of Hartlaub (US 6134470).

Sweeney et al. disclose a cardiac management system that predicts arrhythmias, based on physiological parameter(s) (heart rate), and treats the anticipated occurrence of a cardiac insult with neural stimulation. A warning is provided to the patient that an arrhythmia has been predicted (abstract; col. 1 @ 7-11; col. 2 @ 11-16, 39-45; col. 2 @ 58 – col. 3 @ 8; col. 4 @ 61 – col. 5 @ 20; col. 8 @ 23-55; col. 9 @ 3-32 and 45-62).

As to claims 20, 31 and 32 and the use of the device with the excitable neural tissue of a portion of the spine, Sweeney et al. discloses the use of the device with the excitable neural tissue of a portion of the spine, specifically the stellate ganglion (col. 8 @ 49-53). Note that the concept of using of the device with the excitable neural tissue of a portion of the spine amounts to an intended use limitation of which the device performs or is capable of performing.

As to claims 20, 31 and 32 and closed loop control of the stimulation system, Sweeney et al. disclose closed loop control of the stimulation system that includes the physiological parameter in the loop (abstract; col. 2 @ 46 – col. 2 @ 8; col. 4 @ 61 – col. 5 @ 20).

As to claims 21, 31 and 32 and a drug dispensing apparatus/ means for dispensing biologically-active agents, Sweeney et al. teach the delivery of drugs (col. 22 @ 16-35) as therapy for arrhythmias.

As discussed in the previous five paragraphs of this action, Sweeney et al. disclose the claimed invention except for a drug dispensing apparatus/ means for dispensing biologically-active agents that delivers the drugs via a catheter.

Hartlaub teaches cardiac treatment for cardiac insult (therapy is provided for the precursors to tachyarrhythmias, hence the system anticipates the occurrence of a cardiac insult) using a drug dispenser (col. 5 @ 3-7) for the purpose of adding an additional therapy to treat the patient's condition. Hartlaub incorporates by reference (col. 5 @ 3-13) US 5220917 to Cammilli et al. who teaches a drug dispensing apparatus/ means for dispensing biologically-active agents that delivers the medicament via a catheter (col. 1 @ 62-68). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a drug delivery device that delivers the drugs via a catheter in the Sweeney et al. system in order to use a proven means of cardiac therapy that can effectively treat cardiac dysfunction using an alternate means to electrical stimulation (abstract; col. 1 @ 53-68; col. 5 @ 3-7).

5. Claims 20, 23-24, 26-28 and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmstrom et al. (EP 0 688 577 A1) in view of Hartlaub (US 6134470).

Holmstrom et al. disclose a device for impending supraventricular heart therapy comprising an implantable cardiac and neural electrode system to sense and stimulate (23), a detection block (5) of cardiac (51) and neural (53) sensing circuits to sense the physiological parameter(s), a neural stimulation circuit (9), a control circuit (13), and a pacing circuit (7) (figure 1). The therapy is provided for impending ventricular tachyarrhythmias, hence the system anticipates the occurrence of a cardiac insult. The neural generator includes a time control unit (92) that is programmed, hence the device is capable or teaches neural stimulation prior to onset of the insult, for a period to time after the onset of the insult, or for a time period after termination of the insult. The stimulator can be used externally with external and internal electrodes, read as positioned proximate an external body surface and positioned subcutaneously, respectively (abstract; figure 1; col. 3 @ 6-27 and 37-50; col. 4 @ 1-50; col. 5 @ 10-39; col. 7 @ 43-52; col. 8 @ 10-56; col. 9 @ 10-13 and 40-44).

As to claims 20, 31 and 32 and the use of the device with the excitable neural tissue of a portion of the spine, Holmstrom et al. discloses the use of the device with excitable neural tissue of a portion of the spine, specifically the ganglion stellate (col. 3 @ 6-27; col. 7 @ 50). Note that the concept of using of the device with the excitable neural tissue of a portion of the spine amounts to an intended use limitation of which the device performs or is capable of performing.

As to claims 20, 31 and 32 and closed loop control of the stimulation system, Holmstrom et al. discloses closed loop control of the stimulation system that includes the physiological

As to claims 20, 31 and 32 and closed loop control of the stimulation system, Holmstrom et al. discloses closed loop control of the stimulation system that includes the physiological parameter (vagus heart related nerve signals – heart rate in the loop (col. 2 @ 15-23; col. 4 @ 29-50; col. 5 @ 10-39; col. 6 @ 54 – col. 7 @ 7; col. 7 @ 53 – col. 8 @ 56).

As discussed in the previous four paragraphs of this action, Holmstrom et al. disclose the claimed invention except for a drug dispensing apparatus/ means for dispensing biologically-active agents.

Hartlaub teaches cardiac treatment for cardiac insult (therapy is provided for the precursors to tachyarrhythmias, hence the system anticipates the occurrence of a cardiac insult) using a drug dispenser (col. 5 @ 3-7) for the purpose of adding an additional therapy to treat the patient's condition. Hartlaub incorporates by reference (col. 5 @ 3-13) US 5220917 to Cammilli et al. who teaches a drug dispensing apparatus/ means for dispensing biologically-active agents that delivers the medicament via a catheter (col. 1 @ 62-68). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a drug delivery device that delivers the drugs via a catheter in the Holmstrom et al. system in order to use a proven means of cardiac therapy that can effectively treat cardiac dysfunction using an alternate means to electrical stimulation (abstract; col. 1 @ 53-68; col. 5 @ 3-7).

6. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hartlaub (US 6134470) in view of Krasner et al. (US 3593718). As discussed in paragraph 2 of this action, Hartlaub discloses the claimed invention except for the parameter comprising an increase in the muscle tone of the paraspinal muscles.

Krasner et al. teach physiological monitoring using the increase in the skeletal muscle tone for the purpose of characterizing interrelated physiological functions. The Hartlaub spinal cord lead is implanted such that it is accepted, if the spinal cord lead and the muscle tone sensor are implanted at the same time, the paraspinal muscles would be the skeletal muscles being monitored. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an increase in the muscle tone of the paraspinal muscles in the Hartlaub (US 6134470) in order to recognize the interrelated physiological conditions of tachycardia and increased muscle tone to identify a disturbance of the conduction system that could be related to ischemia (col. 1 @ 29-36; 57-66).

Information Disclosure Statement

7. Parts of the information disclosure statement filed 3/23/06 fail to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609.

The foreign references ("BL – CA") on the information disclosure statement filed 3/23/06 fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed.

The non-patent literature ("EH – DQ") on the information disclosure statement filed 3/23/06 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language.

The information disclosure statement filed 3/23/06 has been placed in the application file with the foreign references ("BL – CA") and the non-patent literature ("EH – DQ") lined through. The lined through reference have not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Statutory Basis

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Frances P. Oropeza
Patent Examiner
Art Unit 3766

8-15-06

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766